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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,937	02/16/2006	Naoki Taoka	05432/100L890-US1	1883

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EXAMINER	
KATAKAM, SUDHAKAR	
ART UNIT	PAPER NUMBER
1621	
MAIL DATE	DELIVERY MODE
11/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,937	TAOKA ET AL.	
	Examiner	Art Unit	
	SUDHAKAR KATAKAM	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 13-111* is/are pending in the application.

4a) Of the above claim(s) *3,6,7,13,15,16,36-50,57-62,69-98 and 108-110* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,8-10,14,17-35,51-56,63-68,99-107 and 111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the application

1. Receipt of Applicant's remarks and arguments filed on 6 July 2009 is acknowledged. The arguments for the rejections are not found persuasive and as such, the rejection made on 12 May 2009 has been maintained.

Response to Arguments

2. Applicant's arguments filed on 6 July 2009 have been fully considered but they are not persuasive for the following reasons:

With regard to 112 1st rejection, applicants' argue that working examples are not required in a patent application, and inventors have identified the minimum percent homology needed for mutants and variants of certain known enzymes to function in the claimed method.

Working examples are not required *if the invention is otherwise disclosed such that one would recognize that applicant was in possession of the full scope of the invention at the time of filing.* In this case, the application fails to describe which enzymes would actually have the properties required to practice the invention by any means. It is well established in the art that the unpredictability of enzyme structure-function correlation. Regarding the minimum percent identity, this argument is not persuasive because the application does not define which structural features are required for enzyme activity. A disclosure of 60% identity is insignificant because many proteins that meet that definition would not have the required activity if the modifications disrupt critical structural features of the enzyme.

While it might be possible to identify the critical residues within the protein by empirical experimentation, however it is not sufficient to disclose a process of obtaining members of the claimed genus. The instant case fails to disclose in specific terms even a single enzymatic acylation using an acylating agent. The teachings of the specification with regard to Pseudomonas sp. lipoprotein, and mutants and variants thereof, are the source for the hydrolase enzyme. Application provides no guidance to how these mutants and variants are source for the hydrolase enzyme. For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only a limited number of species within the genus.

The possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. *Ex parte Kubin*, 83 USPQ2d 1410, 1417 (Bd. Pat. App. & Int. 2007) citing *University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895.

Thus, claiming a method using any enzyme in enzymatic acylation using an acylating agent that achieves a result without defining what means will do is not in compliance with the written description requirement. Rather, it is attempted to preempt the future before it has arrived. With regard to the mutants and variants, failure of the application to disclose which mutants and variants are the source for hydrolase enzyme, the skilled artisan would not have viewed the disclosure as demonstrating possession of the broad scope of any enzyme, and mutants and variants of Pseudomonas sp. lipoprotein thereof, having the source of hydrolase enzyme as recited in the claim.

Therefore, the claims are properly rejected under 35 USC 112 1st paragraph, as lacking adequate written description.

With regard to 103(a) rejection, applicants argue that Boegesoe Reaction Scheme I does not disclose a recemic mixture of citalopram, and the presently claimed formula (II) diol has a significantly different and more complicated structure than any starting substrate in Sturmer.

Boegesoe does teach the isolation of S- or R-citalopram from its racemic mixture [see the Reaction Scheme 1]. Applicants claims do not exclude the ester derivative, because claim language says "comprises", which can be interpreted as the process have additional steps in the reaction. Examiner agrees that Boegesoe do not teach the enzymatic acylation. However, the secondary references cure this deficiency. Sturmer clearly suggested, to a skilled person in the art, that "There is virtually no restriction in relation to the alcohols. Thus, it is possible to use monohydric and polyhydric alcohols such as...." [see col.11, lines 53-65].

Applicants show how the cited references differ from the instant invention, but the obviousness test under 35 U.S.C. 103 is whether the invention would have been obvious in view of the prior art taken as a whole. **In re Metcalf et al. 157 U.S.P.Q. 423**.

Therefore, in view of the above prior art teachings, the examiner asserts that it would have been obvious to a person of ordinary skill in the art, at the time of invention was made, to have combined the teaching of references to make the instantly claimed process with a reasonable expectation of success. The selection of acylating agent, enzyme source and the solvent is within the purview of an ordinary artisan.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2, 4-5, 8-10,14, 17-35, 51-56, 63-68, 99-107 and 111 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for the reasons set forth in the office action dated 12 May 2009.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-2, 4-5, 8-10,14, 17-35, 51-56, 63-68, 99-107 and 111 are again rejected under 35 U.S.C. 103(a) as being unpatentable over **Boegesoe et al** (US 4,943,590) in view of **Sturmer** (US 6,551,806) and **Takano et al** (US 5,219,743), for the reasons set forth in the office action dated 12 May 2009.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no even, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

9. No Claim is allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/
Examiner, Art Unit 1621
/Karl J. Puttlitz/
Primary Examiner, Art Unit 1621